REMARKS

I. Introduction

In response to the Office Action dated December 4, 2002, claims 1-22 have been cancelled, and new claims 23-30 have been added. Claims 23-30 remain in the application. Reconsideration of the application, as amended, is requested.

II. Amendments

Applicants' attorney has made amendments to the claims and specification as indicated above. These amendments were made solely for the purpose of clarifying the language, and do not introduce new matter. Entry of these amendments is respectfully requested.

The amendments to the specification are supported by the application as originally filed and merely correct typographical errors and omissions for which the correct and complete information is readily apparent to one skilled in the art upon reviewing the application as filed.

Support for new claim 23 can be found in previous claim 1, and in Figures 1 and 2.

Support for new claim 24 can be found in previous claims 5 and 8.

Support for new claim 25 can be found in previous claim 9.

Support for new claim 26 can be found in previous claim 13, Examples 2 and 3, and Figures 1, 2, 4, 5 and 6.

Support for new claim 27 can be found in previous claim 16.

Support for new claim 28 can be found in previous claim 20.

Support for new claim 29 can be found in previous claim 18.

Support for new claim 30 can be found in previous claim 22.

III. Restriction Requirement

Applicants gratefully acknowledge the Examiner's withdrawal of the previous restriction requirement on the basis that additional search effort would not be required to examine the claims together. Applicants note that new claims 23-30 are consistent with the prior election of the vaccine of claim 13, and that, as before, all claims can be searched and examined together without undue burden on the Examiner.

IV. Priority

At page 2 of the Office Action, Applicants' claim for foreign priority was acknowledged, and it was noted that the Applicants have not filed a certified English translation copy of the Korean priority application "as required by 35 U.S.C. 119(b)". Applicants respectfully note that 35 U.S.C. §119(b) requires a certified copy of the priority application and an English translation, both of which were provided when the application was filed with the U.S. Patent & Trademark Office on December 6, 2000. For the record, however, Applicants state that, to the best of Applicants' knowledge and belief, the English translation filed on December 6, 2000 is an accurate translation of the Korean priority application.

V. Objections to Specification

At page 3 of the Office Action, the abstract of the disclosure was objected to because it contained three paragraphs. Applicants have submitted a corrected Abstract herewith. The corrected Abstract differs from the original Abstract only in the removal of paragraph breaks.

Also at page 3, the Office Action noted an inconsistency between the results provided in the figures and the identification of Groups 1 and 2 at page 22, lines 6 and 9, of the specification. Applicants appreciate the Examiner's identification of this inadvertent error and suggesting the appropriate correction. Applicants have amended page 22 of the specification accordingly.

Figure 9 was objected to because of inconsistency between the plasmid names used in the figure and the names used in the specification and other figures. In response, Applicants have copied the full plasmid names corresponding to Groups 1-4 from the description of the other figures and added this description to the brief description of Figure 9 appearing at page 10 of the specification. In addition, Applicants have included in this description parenthetical reference to the corresponding abbreviated plasmid names used in Figure 9.

VI. Non-Art Rejections

A. 35 U.S.C. §112, Second Paragraph

At pages 3-5 of the Office Action, claims 2-3, 10-11, 15-16 and 21-22 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite because for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Although Applicants have cancelled the rejected claims, Applicants note that the new claims are in compliance with 35 U.S.C. §112, second paragraph. Specifically, in the new claims, reference to the Figures and the use of "and/or" has been omitted. In addition, new claim 29 has included reference to the applicable base position numbering system identified in the specification at page 12, lines 17-19.

At page 5 of the Office Action, however, claims 3, 11, 16 and 22 were regarded as indefinite because they refer to Accession No. KCTC 0702BP/0703BP. This language appears as well in new claims 27 and 30. It is asserted in the Office Action that it is unclear if the limitation is only for the recited plasmid or includes the deposited cell containing the plasmid. Applicants respectfully maintain that both the claim language and the corresponding text in the specification, at page 13, lines 15-20, are explicit in reciting "the plasmid". It is entirely clear to one skilled in the art that the recitation of "the plasmid" together with the Accession number refers to the plasmid contained within the deposited cell. Applicants maintain that one skilled in the art would have no difficulty or confusion in distinguishing a "plasmid" from a cell.

B. 35 U.S.C. §112, First Paragraph

At pages 5-10 of the Office Action, claims 13 and 15-22 were rejected under 35 U.S.C. §112, first paragraph, because the specification enables a vaccine comprising pTV-SIV/GE+pTV-SIV/pol that prevents SIV infection in rhesus monkeys, but does not reasonably provide enablement for all other vaccines. At pages 10-12 of the Office Action, claims 3, 11, 16 and 22 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. This latter rejection is based on reference to plasmids that may not be readily obtainable by the public in the absence of a deposit.

With regard to the former rejection based on scope of enablement, Applicants note the following with respect to new claim 26, which corresponds most closely to previous claim 13, but with features added to more closely track the vaccines described in the Examples. First, the DNA vaccine of claim 26 comprises two separate plasmids, that is, gag and env genes are carried on a different plasmid than the plasmid that carries the pol gene. Second, the first plasmid carries gag, dpol, env and rev genes without vpr, tat and nef genes. The absence of vpr, tat and nef genes from the plasmid serves to increase the immunogenicity of the DNA vaccine. Third, the second plasmid

carries a signal sequence of a secretory protein and pol gene, which also serves to increase the immunogenicity of the DNA vaccine.

The DNA vaccine of the present invention showed prevention of AIDS in rhesus monkeys when two plasmids were used together (see Group 2 in Fig 4, 5 and 6). The DNA vaccine of the present invention did not show this prevention, however, if the two plasmids were injected with other plasmids carrying cytokine genes (IL-12 and GM-CSF) (see Group 3 in Fig 4, 5 and 6). This result could be explained by Wang J. et al. (Wang J, Roderiquez G, Oravecz T, Norcross MA. Cytokine regulation of human immunodeficiency virus type 1 entry and replication in human monocytes/macrophages through modulation of CCR5 expression. J Virol 1998; 72:7642-7) and Sykes KF et al. (Sykes KF, Lewis MG, Squires B, Johnston SA. Evaluation of SIV library vaccines with genetic cytokines in a macaque challenge Vaccine 2002 May 22;20(17-18):2382-95). As a result, it could be understood that co-delivered cytokines adversely affect DNA immunization.

Accordingly, one skilled in the art would have a reasonable expectation of success in practicing the invention as claimed, wherein the claims encompass the combined plasmid strategy demonstrated to work in the Examples of the specification and with minor variations expected to facilitate immunogenicity (see, e.g., discussion at page 12, line 6, to page 13, line 5).

With regard to the latter rejection, based on the biological deposits identified at page 13, lines 15-20 of the specification, Applicants have amended this portion of the specification to include the address of the depository institution. In addition, Applicants submit herewith a Statement Regarding the Biological Deposits, confirming that these deposits were made under the terms of the Budapest Treaty and that the vectors will be irrevocably and without restriction released to the public upon the issuance of a patent.

VII. Prior Art Rejections

At pages 12-13 of the Office Action, claims 5 and 13 were rejected under 35 U.S.C. §102 as being anticipated by Smith et al. At pages 13-14 of the Office Action, claims 5 and 6 were rejected under 35 U.S.C. §102 as being anticipated by Göttlinger et al. At pages 14-17 of the Office Action, claims 1 and 13 were rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Naldini et al., Weiner et al. and Daniel et al. At pages 17-18 of the Office Action, claims 5 and 8 were rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Göttlinger et

al. and Morris-Vasios et al. At pages 19-20 of the Office Action, claim 9 was rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Göttlinger et al., Morris-Vasios et al. and Hazama et al.

In view of the cancellation of claims 1-22, these rejections are now moot. Moreover, the cited references do not teach or suggest plasmids or vaccines having the features recited in new claims 23-30.

More specifically, Applicants note that the cited references are directed to modifications to lentiviral vectors for the purpose of improved safety for use as transfer vectors for gene therapy. These references lack the teaching or motivation to make modifications that would result in Applicants' claimed invention because the claimed invention includes features designed to improve immunogenicity for use as a vaccine. One skilled in the art would not be motivated to combine features of a gene therapy transfer vector with modifications designed for improved vaccine efficacy, nor would they further combine such features with a vector used merely to study the function of a pol gene product.

For example, the Examiner cites at page 18 of the Office Action that Morris-Vasios et al. teach fusion of the 5' end of the gene encoding avian sarcoma leukosis retrovirus (ASLV) pol-endo protein to a secretory signal sequence of an IL-2 receptor gene to study the function of pol gene product. Yet a person skilled in the art would not select a lethal lentivirus such as SIV for a study of the function of pol gene product. Even if SIV were selected for a study of pol gene product, there would be no motivation to make the particular selection of a plasmid carrying a SIV-derived pol gene encoding for a reverse transcriptase and an integrase, wherein the 5'-end of the pol gene is linked to the signal sequence of a secretory protein.

Likewise, one skilled in the art would not have been motivated to combine the live attenuated SIV vaccine teachings of Daniel et al. wherein nef was deleted for safety reasons to DNA vaccine technology in which the combination of two plasmids is used. Instead, Daniel et al. explicitly teach away from the use of recombinant vaccines (see final column of page 1940 and first column of page 1941).

At page 19 of the Office Action, it is suggested that Hazama provides motivation to combine the teachings of Göttlinger and Morris-Vasios to increase vaccine immunity when using the vector for vaccine. Hazama teaches fusion of IL-2 to a truncated herpes simplex virus (HSV)

type 1 glycoprotein D to increase IL-2 antiviral activity. Applicants respectfully disagree, as the Examiner has provided no reasoning for assuming a relationship between using an HSV protein in an HSV vaccine and using an HSV protein in an SIV vaccine. There is no basis for expecting one to combine the teachings of Hazama, which is directed to enhancing the immune response to glycoprotein D of HSV, with references directed at pol-endo function in ASLV (Morris-Vasios) and pseudotyped lentiviral particles lacking a matrix protein (Göttlinger), to arrive at an improved vaccine for prevention of SIV infection.

Even if one were to combine the teachings of the various cited references, this combination would still not lead to the claimed invention. For example, Applicants respectfully note that Hazama et al. teach fusion of IL-2 to a truncated HSV type 1 glycoprotein D to increase IL-2 antiviral activity. But the truncated gD gene of Hazama encodes amino acids 1-277 (see Materials and Methods/Construction of expression plasmids at page 630). In contrast, the plasmids of the present invention (claims 24 and 25) carry a SIV-derived pol gene and the signal sequence (about 100 base pairs coding 30-40 amino acids) of a secretory protein, such as gD of HSV.

VIII. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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